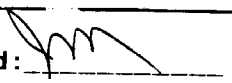
Approved: 

VI. CRITICAL VALUES

ACTIVE REVIEW OR QUALITY IMPROVEMENT MONITORS

Each month, data on turnaround time, culture failure, and clerical errors are compiled, and the results are reported to Laboratory Medicine. Data on banding levels are compiled too. All data are retained in a ringbinder notebook.

Also, one patient is selected at random from each page of the patient log book for assessment of chromosome breakage in 50 cells. A notebook of results is kept.

10 - STEP QUALITY ASSURANCE PLAN
DEPARTMENT OF PEDIATRIC CYTOGENETICS

INDICATOR 1: TURNAROUND TIME

I. ASSIGNMENT RESPONSIBILITY:
The overall responsibility for the quality of patient care (or services) in the Pediatric Cytogenetics Department is assigned to the Medical Director (or director) who directs the sample turnaround time Quality Assurance Program and insures its compliance with the Medical Staff Quality Assurance Plan. Administration of this Pediatric Cytogenetics Quality Assurance Program is assigned to Linda Merryman, Supervisor, to assign responsibilities for data collection and display and reporting to the UTMB Medical Staff Quality Assurance Program.

II. SCOPE OF CARE:
The Pediatric Cytogenetics Department provides the monitoring of sample turnaround time for outpatients and inpatients for the following conditions or diagnoses: Fragile X Syndrome, Turner Syndrome, Klinefelter Syndrome, Prader-Willi Syndrome, Down Syndrome, other trisomies, retinoblastoma, multiple spontaneous abortions, stillbirths, multiple congenital anomalies, sex determination, failure to thrive, microcephaly, mental retardation, primary amenorrhea, gynecomastia, trisomy 8, and leukemias, for example.
Patient Care (or services) in the Pediatric Cytogenetics Department is provided by Drs. Lillian Lockhart and Jerome McCombs, Room C 331, Children's Hospital, UTMB, at the following times: Monday through Friday from 8:00 a.m.- 5:00 p.m.

III. ASPECTS OF SERVICE:
Our goal is to produce the most accurate chromosomal analyses in the shortest period of time, especially in the case of newborns and expectant couples. Important aspects of care will

be chosen on the basis that they are either high-volume, affecting a large number of patients; high risk of serious consequences; or problem-prone, that is, the aspect of care in the past has tended to produce problems for patients or staff.

IV.INDICATOR IDENTIFICATION:
Certain time limits for the completion of a chromosomal study are set and are dependent upon the type of patient sample and the relative urgency of learning the outcome. A time at which the successful completion of a study can first be predicted with confidence is set along with the actual expected completion time.

V. ESTABLISHMENT OF EVALUATION THRESHOLDS:
Our turnaround times for study completion are in agreement with those followed by The Association of Cytogenetic Technologists (Karyogram (15)6, 1989). ACT's guidelines appear in our Quality Assurance Manual.
Our laboratory strives to complete an amniotic fluid study within 2 - 3 weeks. The successful outcome of such a study can be foretold about five days from culture initiation. We try to finish peripheral blood and bone marrow studies in 3 - 4 weeks, respectively. In the case of blood studies, success can be predicted when the slides are first examined under phase microscopy on the fourth day after culture initiation. Same-day feedback is possible with direct bone marrow cultures. We attempt to complete skin fibroblast studies in 4 - 6 weeks; seven days after culture initiation, we can determine if the study will proceed to completion.

VI. DATA COLLECTION/ORGANIZATION:
A daily tissue culture log is maintained on all types of samples obtained for chromosomal analysis. Any problems or possible delays in the predicted schedule of study completion are noted on the log sheets. A special note is entered if sample was considered to be below the usual standards of acceptance upon initial receipt. A less than desirable sample would slow down

our progress with it. The undesirable features of various samples and corrective steps are outlined on pages 8 and 9 of our Quality Assurance Manual.

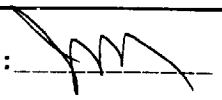
VII.EVALUATION:
Various factors influence our timetable for successful completion of a chromosomal study. As just mentioned, a sub-par sample received at the outset may mean a delay in study completion. The use of outdated culture media or an incubator malfunction, for example, would inhibit cell growth. Careless technique, e.g., infrequent feedings, would delay results. We try to note any such problems in the daily culture logs so that we can later determine why the results came in late in the final analysis.

VIII.CORRECTIVE ACTIONS:
We learn from such lapses with the exception of those factors not under our control. We strive not to repeat any past mistakes in technique which may have led to a delay in study completion. Any problems encountered along the way are noted in the daily tissue culture log along with corrective actions.
Less than desirable samples include bloody amniotic fluid, <15 cc amniotic fluid, blood that was in contact with lithium heparin or EDTA, less than 1 cc of bone marrow aspirate, or skin tissue taken from a deceased infant that had been in formalin or one with necrotic skin.
Bloody amniotic fluid is set up as usual, but, at the first feeding, the RBC's are rinsed away before medium is added. RBC's serve to slow the growth of amniocytes because of nutrient competition.
Blood in lithium heparin or EDTA is exposed to sodium heparin immediately, and cultures are set up right away. Results may or may not be hindered.
A direct and an overnight culture are established even though we receive only 1 cc of bone marrow. If enough metaphases are not obtained, the whole process is slowed down when we are

forced to ask for another bone marrow sample.
Organ tissue is obtained from formalin-exposed or necrotic infants. It has been our experience that organ tissue either will not grow or it will grow more slowly than skin fibroblasts. Flawed culture media, incubators, or technique tend to retard cell growth and delay final results. The "shelf life" of our complete Chang, Amniomax, RPMI 1640 (blood), RPMI 1640 (bone marrow), and MEM media are one week, 10 days, two weeks, and three weeks, respectively. We strive to adhere to these limits. A daily record is kept of the incubator temperature and CO_2 levels; any deviations are responded to immediately. Care is taken to insure that the CO_2 supply to an incubator does not run out. We try to be very careful with our tissue culture technique to prevent mistakes and resultant delays.

IX.ACTION DOCUMENTATION:
Daily tissue culture logs are carefully maintained in detail as are the incubator temperature and CO_2 readings. The laboratory supervisor checks and initials these records and suggests corrective actions if necessary to keep the studies progressing along as smoothly as possible.

X. COMMUNICATION TO ORGANIZATION:
Our quality assurance guidelines and records are made available to authorized interested parties on request. These results are also reported to the Hospital QA departmental office. They are discussed in monthly QA meetings in the Department of Laboratory Medicine.

Approved: 

10- STEP QUALITY ASSURANCE PLAN
DEPARTMENT OF PEDIATRIC CYTOGENETICS

INDICATOR III: MISTAKES OF LOGGED TEST RESULTS

I. ASSIGNMENT RESPONSIBILITY:

The overall responsibility for the quality of patient care (or services) in the Pediatric Cytogenetics Department is assigned to the Medical Director (or director) who directs the chromosome banding resolution Quality Assurance Program and insures its compliance with the Medical Staff Quality Assurance Plan.
Administration of the Pediatric Cytogenetics Quality Assurance Program is assigned to SHALONDA TURNER, cytogenetics TECHNOLOGIST,to assign responsibilities for data collection and display and reporting to the UTMB Medical Staff Quality Assurance Program.

II. SCOPE OF CARE:

The Pediatric Cytogenetics Department provides the monitoring of banding resolution for outpatients and inpatients for the following conditions or diagnoses: Fragile X Syndrome, Turner Syndrome, Klinefelter syndrome, Prader-Willi Syndrome, Down syndrome, other trisomies, retinoblastoma, multiple spontaneous abortions, stillbirths, multiple congenital anomalies, sex determination, failure to thrive, microcephaly, mental retardation, primary amenorrhea, gynecomastia, trisomy 8, and leukemias, for example.

Patient Care (or services) in the Pediatric Cytogenetics Department is provided by Drs. Lillian Lockhart and Jerome McCombs, Room C 331 Children's Hospital, UTMB, at the following times: Monday through Friday from 8:00 a.m. - 5:00

p.m.

III. ASPECTS OF SERVICE:

Our goal is to try to eliminate clerical errors. This indicator was chosen to insure accurate results to the primary physician.

IV. INDICATOR IDENTIFICATION:

Criteria to be examined include: correlation of patient name and lab number, correctly reported sex compared to chromosomal results, correct reporting of any chromosome abnormalities.

V. ESTABLISHMENT OF EVALUTION THRESHOLDS:

We will strive to eliminate all clinical errors in our results; our acceptable error rate will be <1%.

VI. DATA COLLECTION:

Data will be collected by lab technologist every two weeks and reported to supervisor. In turn, data will be presented monthly to lab director. Any discrepancy will be reported to the director immediately and appropriate action taken as soon as possible.

VII. EVALUATION:

Acquired data will be used to evaluate the proficiency of our reporting scheme and based on the individual examination

of each final report.

VIII. CORRECTIVE ACTION:

Corrective actions will be appropriate for the error; e.g., misreported results: 1) Immediate notification to referring physician, correction reported to medical records with removal of inaccurate data; 2) wrong UH# / wrong DOB / wrong date received: This information will be corrected and forwarded to chart in medical records.

IX. ACTION DOCUMENTATION:

A. Director will produce Exceptional Case Record in final report.
B. Inclusion of data in final report.
C. Notification of referring physician. Final report and preliminary phone conversation with appropriate documentation.

Exceptional report log will be maintained and available for examination.

X. COMMUNICATION TO ORGANIZATION:

Thorough monthly reports to Hospital Quality Assurance

program.

HEALTH INFORMATION

IMMUNIZATION REQUIREMENTS, UTMB, GALVESTON, TX
EMPLOYEE AND STUDENT IMMUNIZATION RECORD
UNIVERSITY HEALTH SERVICE

Prospective UTMB students, Galveston College Health Programs students, and employees: Your health coverage will not be in effect until entrance immunization and skin test requirements have been met. (If you are (were) presently _____, previously _____, employed or enrolled at UTMB, check here. Your old record will be continued. Go to B. below.)

A.THESE MUST BE COMPLETED IN ADVANCE. Please have your physician use the attached form in recording this immunization and skin test information.

REQUIRED---	TETANUS:	Full course, or booster dose toxoid within a minimum of ten years if previously given full course.
REQUIRED---	DIPHTHERIA:	Full course of diphtheria toxoid, or booster within a minimum of ten years if previously given full course (required).
REQUIRED---	MUMPS, MEASLES, RUBELLA	Please record history of illness, titer and/or vaccine by date.
REQUIRED---	PPD 5TU TUBERCULIN SKIN TEST AND READING	

B. THE FOLLOWING ARE NOT REQUIRED, but information is requested:

HEPATITIS B VACCINE:	Record history or illness, screening test and results, and/or vaccine by date.
POLIO:	Not required if oral polio vaccine administered previously. Please

INFLUENZA VACCINE: record history of / or vaccine. Yearly

RETURN TO:

UTMB EMPLOYEE HEALTH CENTER
ROOM 2.400 TRAUMA CENTER, Route J-74
UNIVERSITY OF TEXAS MEDICAL BRANCH
GALVESTON, TEXAS 77550

prior to matriculation. It will be used as part of your health record here.